

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Richmond Division**

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PATIENT SERVICES, INC., )  
Plaintiff, )  
v. ) Case No. 3:18-cv-0016 (MHL)  
UNITED STATES OF AMERICA, *et al.*, )  
Defendants. )  
\_\_\_\_\_  
)

**ANSWER**

Defendants hereby answer Plaintiff's Complaint for Declaratory Judgment and Injunctive Relief ("Complaint") as follows:

The first unnumbered paragraph is a description of Plaintiff's lawsuit to which no response is required.

1. Defendants lack knowledge or belief sufficient to admit or deny the first and second sentences. Defendants deny the third sentence.

2. With regard to the first sentence, Defendants admit that the Department of Health and Human Service's ("HHS's") Office of Inspector General ("OIG") issued an OIG advisory opinion to Plaintiff in 2002, OIG Advisory Opinion No. 02-01 ("2002 Advisory Opinion") and issued a Modification of OIG Advisory Opinion No. 02-01 to Plaintiff in 2017 ("Modification of 02-01). As for the remainder of the first sentence, Defendants lack knowledge or belief sufficient to admit or deny whether Plaintiff "operated under an OIG opinion and ensured that its various funds provided support to government beneficiaries without regard to the patient's choice of product or choice of provider, respecting the treatment decisions made by independent practitioners." Defendants deny the second sentence. The third sentence contains (i) a

characterization of the suit to which no response is required and (ii) an allegation regarding Plaintiff's motivation for the lawsuit, as to which Defendants lack knowledge or belief sufficient to allow them to admit or deny it.

3. This paragraph is a characterization of Plaintiff's lawsuit to which no response is required.

4. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the first sentence. The second sentence is a characterization of documents in the Federal Register to which no response is required. Defendants deny the third sentence.

5. Deny.

6. Deny.

7. The first sentence contains legal conclusions regarding the meaning of the Modification of 02-01 to which no response is required. Defendants lack knowledge or belief sufficient to admit or deny the second sentence.

8. Defendants deny this allegation.

9. The first sentence contains legal conclusions to which no response is required.

Defendants lack knowledge or belief sufficient to admit or deny the second sentence. With regard to the third sentence, Defendants admit that on November 28, 2017, OIG issued a Final Notice of Rescission of OIG Advisory Opinion No. 06-04. The Final Notice is available at:

<https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpnRescission06-04.pdf>. OIG determined that the public interest required OIG to rescind OIG Advisory Opinion No. 06-04. OIG made the determination to rescind OIG Advisory Opinion No. 06-04 based on the entity's failure to fully, completely, and accurately disclose all relevant and material facts to OIG in

accordance with 42 C.F.R. § 1008.45. With regard to the fourth sentence, OIG lacks sufficient knowledge to admit or deny the allegations.

10. With regard to the first clause of the first sentence, Defendants deny that the 2002 Advisory Opinion and Modification of 02-01 govern how Plaintiff should operate and lack knowledge or belief sufficient to admit or deny whether “PSI is committed to compliance with OIG’s pre-existing published Advisory Opinion.” With regard to the second clause of the sentence, Defendants admit that the 2002 Advisory Opinion did not infringe Plaintiff’s First Amendment rights. Defendants deny the second and third sentences.

11. Defendants deny the first and second sentences. The third sentence is a legal conclusion to which no response is required. Defendants deny the fourth sentence. Defendants lack knowledge or belief sufficient to admit or deny the fifth sentence. Defendants deny the sixth sentence.

12. Deny.

13. Defendants admit that PSI is registered as a 501(c)(3) organization. Defendants lack knowledge or belief sufficient to admit or deny the second sentence.

14. Defendants admit the first and third sentences. With respect to the second sentence, Defendants admit that OIG is an independent and objective oversight unit of HHS.

15. Defendants deny this paragraph. OIG was established by law as an independent and objective oversight unit of HHS to carry out the mission of preventing fraud and abuse and promoting economy, efficiency, and effectiveness of HHS programs and operations. In accordance with section 1128(D)(b) of the Social Security Act (42 U.S.C. 1320a-7d(b)) and 42 C.F.R. part 1008, OIG issues advisory opinions, in consultation with DOJ, about the application of the Federal Anti-kickback Statute, a criminal statute (42 U.S.C. § 1320a-7b(b)), and OIG's

other fraud and abuse authorities to the requesting party's existing or proposed business arrangement. OIG's headquarters are located in Washington, D.C. at 330 Independence Ave., S.W., Room 5250, Washington, D.C. 20201.

16. Defendants admit the first and third sentences. Footnote one is a quotation from 5 U.S.C. § 702 to which no response is required. Defendants admit the second sentence. The fourth sentence is a characterization of this lawsuit to which no response is required.

17. Defendants deny the first sentence: Alex M. Azar II is the Secretary of Health and Human Services, and is substituted as a defendant in this action in his official capacity. Defendants deny the second sentence. Defendants deny the third sentence, but aver that that Secretary Azar's office is at 200 Independence Ave., SW, Washington, D.C. 20201. The last sentence is a characterization of this action to which no response is required.

18. This paragraph is a characterization of Plaintiff's lawsuit to which no response is required.

19. This paragraph contains legal conclusions to which no response is required.

20. This paragraph contains legal conclusions to which no response is required.

21. This paragraph contains a legal conclusion to which no response is required.

Roman numeral I between paragraphs 21 and 22 is a legal conclusion to which no response is required.

22. This paragraph contains quotation of an excerpt of the First Amendment to which no response is required.

23. The first and third sentences of this paragraph contain legal conclusions to which no response is required. The second sentence is quotation from *Reed v. Town of Gilbert*, 135 S.Ct. 2218, 2227 (2015), to which no response is required.

24. This paragraph contains a characterization of *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), to which no response is required.

25. This paragraph contains characterizations of, and quotations from, *Sorrell*, to which no response is required.

26. This paragraph contains legal conclusions, case citations, and quotations from *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1984) and *Sorrell* to which no response is required.

27. This paragraph contains legal conclusions, case citations, and quotations from *Secretary of State of Maryland v. Joseph H. Munson Co.*, 467 U.S. 947 (1984) to which no response is required.

28. This paragraph contains legal conclusions, case citations, and quotations from *Riley v. Nat'l Federation of the Blind*, 487 U.S. 781 (1988), and *Village of Schaumburg v. Citizens for a Better Environment*, 444 U.S. 620 (1980), to which no response is required.

29. This paragraph contains a quotation of an excerpt of *Schaumburg*, to which no response is required.

30. The first sentence of this paragraph contains a legal conclusion to which no response is required. As to the second sentence, Defendants deny the allegation that the 2002 Advisory Opinion, as modified in 2017 by the Modification of 02-01 with Plaintiff's consent, imposes restrictions on speech; it instead includes factual certifications made by Plaintiff with knowledge of the penalties for false statements provided by 18 U.S.C. § 1001. With regard to the remainder of the second sentence, Defendants lack knowledge or belief sufficient to admit or deny whether Plaintiff's agreement to the facts it certified in 2017 "crippled [its] ability to

establish new disease funds or to modify existing disease funds.” Defendants lack knowledge or belief sufficient to admit or deny the third sentence.

31. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

32. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

33. Defendants deny the allegation that the Modification of 02-01 imposes “restrictions on the free flow of information”; OIG relied on facts certified by Plaintiff regarding how Plaintiff intended to operate its PAP when issuing the Modification of 02-01. Defendants lack knowledge or belief sufficient to admit or deny the remainder of this paragraph.

34. The first sentence of this paragraph contains a legal conclusion regarding the “chill imposed on PSI’s communications” to which no response is required; Defendants lack knowledge or belief sufficient to admit or deny the remainder of the allegations in the first sentence. The second sentence contains a quotation of an excerpt from *Schaumburg* to which no response is required. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the third sentence. The last sentence consists of a citation to which no response is required.

Roman Numeral II between paragraphs 34 and 35 is a legal conclusion to which no response is required.

35. This paragraph contains legal conclusions and citations to which no response is required.

36. This paragraph contains legal conclusions and citations to which no response is required.

37. This paragraph contains legal conclusions to which no response is required.
38. This paragraph contains legal conclusions and citations to which no response is required.
39. This paragraph and footnote two contain legal conclusions and citations to which no response is required.
40. This paragraph contains legal conclusions and citations to which no response is required.
41. This paragraph contains legal conclusions and citations to which no response is required.
42. This paragraph contains legal conclusions and citations to which no response is required.
43. This paragraph contains legal conclusions and citations to which no response is required.
44. This paragraph contains legal conclusions and citations to which no response is required.
45. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the first, third, fourth, and fifth sentences of this paragraph. The second sentence contains legal conclusions to which no response is required.
46. This paragraph contains a characterization of and a quotation to a portion of the Federal Register to which no response is required.
47. The first sentence is a characterization of this lawsuit to which no response is required. Defendants lack knowledge or belief sufficient to admit or deny the remainder of the paragraph.

48. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

49. As to the first sentence, OIG denies this sentence. OIG made the determination to rescind OIG Advisory Opinion No. 06-04 based on the entity's failure to fully, completely, and accurately disclose all relevant and material facts to OIG in accordance with 42 C.F.R. § 1008.45. Defendants admit the second sentence. As to the third sentence, Defendants admit that the OIG rescinded OIG Advisory Opinion No.06-04, but deny the allegations of that sentence to the extent that they suggest that OIG should not rescind an advisory opinion if rescission would lead the PAP that had received the opinion to cease operations. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the fourth sentence.

Roman numeral III between paragraphs 49 and 50 contains a characterization of Plaintiff to which no response is required.

50. Defendants admit that PSI is registered as a 501(c)(3) organization; Defendants lack knowledge or belief sufficient to admit or deny the allegations in the remainder of this paragraph.

51. Defendants admit that Dana A. Kuhn, Ph.D., is President and Founder of Plaintiff, with respect to the rest of the paragraph, Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

52. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

53. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

54. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

55. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

56. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

57. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

58. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

59. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

60. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph. The footnote contains a citation to which no response is required.

61. To the extent the first sentence contains an allegation regarding what is “required by OIG’s pre-existing guidance,” it is a legal conclusion to which no response is required; Defendants lack knowledge or belief sufficient to admit or deny the allegations of the remainder of the first sentence. Defendants lack knowledge or belief sufficient to admit or deny the second sentence. The third sentence consists of a citation to the Federal Register to which no response is required.

62. To the extent the paragraph contains an allegation regarding what is “prescribed by the 2017 Modified Advisory Opinion,” it is a legal conclusion to which no response is

required. Defendants lack knowledge or belief sufficient to admit or deny the allegations of the remainder of this paragraph.

63. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the first sentence of this paragraph. The second sentence contains citations to an exhibit and the Federal Register to which no response is required.

64. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph. The second sentence contains citations to an exhibit and to the Federal Register to which no response is required.

65. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph. The footnote contains a citation to which no response is required.

66. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the first sentence of this paragraph. The footnote contains a citation to which no response is required.

67. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

68. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the first sentence of this paragraph.

69. Defendants lack knowledge or belief sufficient to admit or deny whether “PSI was one of the first organizations to provide assistance of this kind[.]” Defendants admit that “a number of other charitable organizations now [ ] provide financial assistance through disease funds to indigent individuals facing high health care costs.”

70. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

71. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

72. To the extent the first sentence contains a legal conclusion regarding what is “permitted by” or “consistent with” “OIG guidance,” no response is required. With regard to the allegation in the first sentence that “donors often earmark their contribution for specific disease funds,” Defendants lack knowledge or belief sufficient to admit or deny the allegation. The second sentence contains a legal conclusion to which no response is required, and the third sentence contains citations to which no response is required.

73. This paragraph contains a characterization of Plaintiff to which no response is required.

74. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

Roman Numeral IV between paragraphs 74 and 75 contains legal conclusions to which no response is required.

75. Defendants admit that OIG issued the 2002 Advisory Opinion and respectfully direct the Court to that opinion, attached as Exhibit A to Plaintiff’s Complaint, for a full and accurate statement of its contents.

76. This paragraph contains a characterization of the 2002 Advisory Opinion to which no response is required.

77. The first sentence of this paragraph contains a characterization of the 2002 Advisory Opinion to which no response is required. The second sentence contains a legal conclusion to which no response is required.

78. Defendants admit that OIG has issued more than 18 advisory opinions to “charities” of many types including but not limited to PAPs. Defendants also admit that in 2005 OIG issued a “Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees” (available at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf> and subsequently published in the Federal Register at 70 Fed. Reg. 70623 (Nov. 22, 2005)) and that in 2014 OIG issued a “Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs.” The Supplemental Bulletin is available at:

<http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf> and was subsequently published in the Federal Register at 79 Fed. Reg. 31120 (May 30, 2014). The second and third sentence, as well as footnote seven, contain legal conclusions and citations to other advisory opinions and portions of the Federal Register to which no response is required.

79. This paragraph contains a characterization of, and quotations from, documents in the Federal Register to which no response is required.

80. Defendants admit the first sentence of this paragraph. The second sentence contains a citation to which no response is required. The remainder of this paragraph contains a characterization of, and quotations from, documents in the Federal Register to which no response is required.

81. With regard to the first sentence of this paragraph, Defendants admit that, following its issuance of a Supplemental Special Advisory Bulletin in 2014, OIG contacted Plaintiff about modifying its 2002 Advisory Opinion to align with OIG’s current guidance, but deny the remainder of the allegations. With regard to the second sentence, Defendants admit that OIG and PSI discussed modifications to Advisory Opinion 02-01, but deny that the discussions

stretched over a period of months, and instead aver that they stretched for years. Defendants lack knowledge or belief sufficient or deny the allegations in the third and fourth sentences, except to deny the allegations in these sentences to the extent they suggest that any aspect of the opinion OIG proposed would “prevent[] communications” or violate the First Amendment.

82. Defendants deny this paragraph.

83. Defendants admit that OIG issued the Modification of 02-01 on March 3, 2017.

Defendants deny that they “imposed” the modifications. The remainder of this paragraph contains Plaintiff’s characterization of the opinion to which no response is required.

84. With regard to the first sentence, Defendants deny that OIG “required” PSI to agree to “nearly two dozen” factual certifications; with regard to the remainder of the first sentence, Defendants lack knowledge or belief sufficient to admit or deny whether Plaintiff “needs” the advisory opinion “to operate as a charitable fund.” The second sentence contains a citation to which no response is required. The third sentence is a characterization of Plaintiff’s lawsuit to which no response is required.

85. The first two sentences of this paragraph contains Plaintiff’s characterizations of its lawsuit to which no response is required. The third sentence contains a citation to which no response is required. The fourth sentence is a legal conclusion regarding the meaning of the Modification of 02-01 to which no response is required.

86. The first sentence of this paragraph contains Plaintiff’s characterization of its lawsuit to which no response is required. The second sentence is a citation to which no response is required. The third sentence is a legal conclusion regarding the meaning of the Modification of 02-01 to which no response is required.

87. The first sentence of this paragraph contains Plaintiff's characterization of its lawsuit to which no response is required. The second sentence is a citation to which no response is required.

88. Deny.

89. This paragraph is a characterization of the Modification of 02-01 to which no response is required. Defendants deny the allegations to the extent they allege that OIG "required a certification" and that the cited portion of the Modification of 02-01 violates the First Amendment.

90. This paragraph is a characterization of the Modification of 02-01 to which no response is required. Defendants deny the allegations to the extent they allege that OIG "required a certification" and that the cited portion of the Modification of 02-01 violates the First Amendment.

91. This paragraph is a characterization of the Modification of 02-01 to which no response is required. Defendants deny the allegations to the extent they allege that OIG "required a certification" and that the cited portion of the Modification of 02-01 violates the First Amendment.

92. Defendants admit the first sentence of this paragraph. With regard to the second sentence, Defendants deny the allegation that Modification of 02-01 "explicitly and directly prohibits significant categories of communications, among PSI and donors, prospective donors, or their purported affiliates" and lack knowledge or belief sufficient to admit or deny the remainder of the allegations of this sentence.

93. This paragraph contains legal conclusions to which no response is required.

94. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

95. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

96. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

97. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

98. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

99. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

100. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

101. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

102. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the first two sentences of this paragraph. The third sentence contains legal conclusions to which no response is required.

103. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

104. Defendants admit that OIG issued Advisory Opinion No. 02-1 in 2002 (the 2002 Advisory Opinion), which remained in place until the Modification of 02-01 was issued on

March 3, 2017, and that the 2002 Advisory Opinion did not include the certifications that Plaintiff challenges in this lawsuit. Defendants, however, deny the allegation that OIG “permitted” the Plaintiff to engage in certain speech; communications with “donors, prospective donors, and their purported affiliates” were not addressed.

105. Defendants deny that OIG, through the Modification of 02-01, “required” that Plaintiff refrain from any speech; Defendants lack knowledge or belief sufficient to admit or deny whether the communications that Plaintiff describes “allow PSI to gather the critical information necessary to determine whether Plaintiff should establish a new fund for a disease.”

106. Deny.

107. Deny.

108. Deny.

109. This paragraph contains Plaintiff’s characterization of the Modification of 02-01, citations, and legal conclusions to which no response is required.

110. Defendants lack knowledge or information sufficient to form a belief as to the hypothetical scenario described in the first two sentences of this paragraph. With regard to the third sentence, Defendants admit that OIG did not provide Plaintiff any further definition of the meaning of the Modification of 02-01 beyond the text of that opinion, but lack knowledge or belief sufficient to admit or deny how Plaintiff interpreted this response or how it interprets the term “affiliate.”

111. Deny.

112. Deny.

113. Deny.

114. Deny.

115. To the extent Plaintiff alleges that the Modification of 02-01 restricts Plaintiff's communications, Defendants deny the allegation because the Modification of 02-01 does not impose restrictions on speech. Defendants lack knowledge or belief sufficient to admit or deny the remainder of the allegations in this paragraph regarding what Plaintiff is "in the dark about" or what its "critical source[s] of information" are.

116. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the first and third sentences. As to the second sentence, Defendants deny the allegation that the Modification of 02-01 restricts any communications and lack knowledge or belief sufficient to admit or deny the remainder of the allegations.

117. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

118. With regard to the first sentence of this paragraph, Defendants deny that the Modification of 02-01 imposes any restrictions on speech, and lack knowledge or belief sufficient to admit or deny the consequences that Plaintiff speculates will "most likely result" from the opinion. Defendants lack knowledge or belief sufficient to admit or deny the allegations in the second sentence.

119. Defendants lack knowledge or belief sufficient to admit or deny the allegations in this paragraph.

120. This paragraph contains legal conclusions to which no response is required.

121. With regard to the first sentence of this paragraph, Defendants deny that the Modification of 02-01 prevents the Plaintiff from engaging in any communications. As to the second sentence, Defendants lack knowledge or belief sufficient to admit or deny how concerned Plaintiff is about violating the terms of the Modification of 02-01.

122. The first sentence of this paragraph contains a legal conclusion to which no response is required. Defendants deny the allegations in the second sentence. The third sentence contains a citation to which no response is required. As to the fourth sentence, Defendants admit that on November 28, 2017, OIG issued a Final Notice of Rescission of OIG Advisory Opinion No. 06-04 as OIG determined that the public interest required OIG to rescind OIG Advisory Opinion No. 06-04. OIG made the determination to rescind OIG Advisory Opinion No. 06-04 based on the entity's failure to fully, completely, and accurately disclose all relevant and material facts to OIG in accordance with 42 C.F.R. § 1008.45.

123. This paragraph contains legal conclusions and case citations to which no response is required.

124. This paragraph contains legal conclusions to which no response is required.

The unnumbered subheading under "Count I," between paragraphs 124 and 125, contains legal conclusions and a request for relief to which no response is required.

125. This paragraph merely incorporates by reference the allegations in the preceding paragraphs. To the extent a response is deemed necessary, Defendants refer the Court to their responses to the referenced paragraphs.

126. This paragraph contains Plaintiff's characterization of the Administrative Procedure Act to which no response is required.

127. This paragraph contains legal conclusions to which no response is required.

128. This paragraph contains legal conclusions to which no response is required.

129. This paragraph contains legal conclusions regarding the meaning of the Modification of 02-01 to which no response is required.

130. This paragraph contains legal conclusions to which no response is required.

131. This paragraph contains legal conclusions to which no response is required.
132. This paragraph contains legal conclusions to which no response is required.
133. This paragraph contains legal conclusions to which no response is required.
134. This paragraph contains legal conclusions to which no response is required.
135. This paragraph contains legal conclusions to which no response is required.
136. This paragraph consists of legal conclusions and a request for relief to which no response is required.

The unnumbered subheading under “Count II,” between paragraphs 136 and 137, contains legal conclusions to which no response is required.

137. This paragraph merely incorporates by reference the allegations in the preceding paragraphs. To the extent a response is deemed necessary, Defendants refer the Court to their responses to the referenced paragraphs.

138. This paragraph contains Plaintiff’s characterization of the Administrative Procedure Act to which no response is required.

139. This paragraph contains legal conclusions to which no response is required.

140. This paragraph contains legal conclusions to which no response is required.

141. This paragraph contains legal conclusions regarding the meaning of the Modification of 02-01 to which no response is required.

142. Defendants deny the allegations in the first sentence of this paragraph. The second sentence contains legal conclusions to which no response is required.

143. Defendants lack knowledge or belief sufficient to admit or deny the allegation that Plaintiff has “ceased” various “communications with donors, prospective donors and their

affiliates; Plaintiff's allegations that these communications are/were "lawful, truthful and non-misleading" are legal conclusions to which no response is required.

144. This paragraph contains legal conclusions to which no response is required.

145. This paragraph contains legal conclusions to which no response is required.

146. This paragraph contains legal conclusions to which no response is required.

147. This paragraph contains legal conclusions to which no response is required.

148. This paragraph contains legal conclusions to which no response is required.

149. This paragraph contains legal conclusions to which no response is required.

150. This paragraph contains a request for relief to which no response is required.

The remaining unnumbered paragraph, including subparts (a) through (d), constitutes a prayer for relief to which no response is required. To the extent a response is required, Defendants deny that Plaintiff is entitled to the relief requested or to any relief whatsoever.

Defendants hereby deny all allegations in Plaintiff's Complaint not expressly admitted or denied.

#### **Affirmative Defenses**

1. Plaintiff's complaint fails to state a claim upon which relief can be granted.
2. Defendants' actions are fully consistent with applicable law.
3. Plaintiff consented to enter into the Modification of 02-01, and thereby waived any challenge to its validity.

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April 26, 2018

Respectfully submitted,

TRACY DOHERTY-MCCORMICK  
Acting United States Attorney

CHAD READLER  
Acting Assistant. Attorney General  
Civil Division

JOEL McELVAIN  
Assistant Director, Federal Programs Branch

JUSTIN M. SANDBERG  
Senior Trial Counsel

R. CHARLIE MERRITT  
Trial Attorney

Federal Programs Branch  
Civil Division, Department of Justice  
20 Mass. Ave. NW, Rm. 7302  
Washington, D.C. 20001  
Phone: (202) 514-5838; (202) 616-8098  
Email: [justin.sandberg@usdoj.gov](mailto:justin.sandberg@usdoj.gov);  
[robert.c.merritt@usdoj.gov](mailto:robert.c.merritt@usdoj.gov)

/s/

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Jonathan H. Hambrick  
Virginia State Bar No. 37590  
Office of the United States Attorney  
919 E. Main St., Suite 1900  
Richmond, VA. 23219  
Tel: (804) 819-5400  
Fax: (804) 771-2316  
[jay.h.hambrick@usdoj.gov](mailto:jay.h.hambrick@usdoj.gov)

*Attorneys for Defendants*